

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION**

United States of America, <i>et al.</i> ,)	Civil Action No. 9:14-230-RMG
)	
Plaintiffs,)	
)	
<i>ex rel.</i> Scarlett Lutz, <i>et al.</i> ,)	ORDER AND OPINION
)	
Plaintiffs-Relators,)	
v.)	
)	
Berkeley Heartlab, Inc., <i>et al.</i> ,)	
)	
Defendants.)	
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This matter is before the Court on the Government’s requested jury instruction number 2.9 and Defendants’ requested jury instruction number 19, which relate to the requirement that a claim violative of the False Claims Act (“FCA”) must be false in a way that is material to the Government’s payment decision. For the reasons set forth below, the Court will substantially charge the Government’s requested instruction and will decline to charge Defendants’ requested instruction.

I. Discussion

Under the FCA, a misrepresentation must be material to the Government’s decision to pay the claim. *See Universal Health Servs., Inc. v. United States ex. rel. Escobar*, 136 S. Ct. 1989, 2001 (2016) (“*Escobar*”). The Supreme Court reserved whether the materiality requirement is governed by § 3729(b)(4) or by the common law, *id.* at 2002, but in this case, the parties agree that materiality should be defined by § 3729(b)(4) (*see* Dkt. Nos. 631 at 19, 644 at 19). The standards are essentially equivalent. *Escobar*, 136 S. Ct. at 2002. A misrepresentation is material if knowledge of the truth would have caused the Government not to pay the claim. *See id.* at 2002–

03. It is insufficient that knowledge of the truth merely would have given the Government discretion not to pay the claim. *Id.* at 2003.

The allegedly false claims in this case involve allegations of violations of the Anti-Kickback Statute (“AKS”) and allegations that ordered tests were medically unnecessary. The Government requests the jury be charged that whether a laboratory service resulted from an AKS violation, or whether a laboratory service was medically unnecessary, is material, as a matter of law, to the Government’s decision to pay claims for such services. (Dkt. No. 631 at 19.) Defendants request the jury be charged that if the Government pays a claim for laboratory services with actual knowledge that the services resulted from an AKS violation or were medically unnecessary, that is “strong evidence” the FCA’s materiality requirement has not been met. Defendants further want the Court to charge the jury, “If you find that the Government knew about the underlying facts about the Defendants’ alleged fraudulent conduct, but continued to pay claims submitted, you must find for the Defendants.” (Dkt. No. 644.)

For the reasons set forth below, the Court rules that the Government’s proposed jury instruction correctly states the law, and that Defendants’ proposed jury instruction misstates the law.

A. Anti-Kickback Statute Compliance

In the Patient Protection and Affordable Care Act (“PPACA”), Congress provided that “a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 132a-7b] constitutes a false or fraudulent claim.” 42 U.S.C. § 1320a-7b(g), *as amended by* PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010). That language became effective on March 23, 2010. The purpose of the change was to clarify that a claim resulting from a kickback does not become eligible for payment when an innocent third party submits the claim. *See United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 334 (S.D.N.Y.

2014) (quoting 155 Cong. Rec. S10852–01, 2009 WL 3460582 (statement of Senator Kaufman)). Further, “the 2010 amendment made clear that compliance with the AKS is a precondition to the payment of claims submitted to these programs, and not merely a condition of participation in the programs.” *Id.* at 331.

Although the provision that a claim is false and fraudulent if it results from an AKS violation does not explicitly state that the AKS violation is material to the Government’s payment decision, the only reasonable inference is that AKS violations are *per se* material. Providing that AKS compliance is a condition of payment and that a tainted claim is ineligible for reimbursement even when submitted by an innocent party clearly demonstrates Congress’s intent that AKS compliance is material to payment decisions in all cases. *Cf. United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 812 (S.D.N.Y. 2017), *appeal docketed*, No. 17-2191 (2d Cir. July 17, 2017) (the district court’s ruling on materiality of AKS violations is not an issue on appeal). The Court therefore holds that for claims after March 23, 2010, AKS compliance is *per se* material to payment decisions.

Further, the Court holds that AKS compliance was *per se* material even before the PPACA. This Court, like the *Wood* court, “has no trouble concluding that compliance with the AKS is a ‘material’ condition of payment” before March 23, 2010. *Id.*; *see also United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 394–95 (1st Cir. 2011); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259–60 (11th Cir. 2005). Compliance is “material” if it has “a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). In other words, the “matter is material”

when “a reasonable man would attach importance to [it] in determining his choice of action in the transaction” (internal quotations omitted)). *Escobar*, 136 S. Ct. at 2002–03.

No reasonable person could believe that AKS compliance is unimportant to the Government’s reimbursement decisions for laboratory services. The “holistic” materiality analysis the Supreme Court set forth in *Escobar* demonstrates that AKS compliance is *per se* material. In *Escobar*, the Supreme Court held that several factors are considered in determining materiality: (1) whether compliance with a statute is a condition of payment, (2) whether the violation goes to “the essence of the bargain” or is “minor or insubstantial,” (3) whether the Government consistently pays or refuses to pay claims when it has knowledge of similar violations, and (4) whether the Government would likely refuse payment had it known of the violation. 135 S. Ct. at 2003–04.

Each factor demonstrates the *per se* materiality of AKS compliance. Courts have long held that AKS compliance is a condition of payment. *See Kester*, 41 F. Supp. 3d at 330 (collecting cases). Violation of the AKS is not a *de minimis* regulatory violation, nor is it a mere technical violation of adhesive fine print in Government contracts. It is a felony punishable by five years in prison, and it requires the violator to act “knowingly and willfully.” 42 U.S.C. § 1320a–7b. The Government routinely punishes AKS violations through criminal proceedings and civil proceedings to recoup funds. *See, e.g., United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *Wood*, 246 F. Supp. 3d 772; *United States ex rel. Williams v. Health Mgmt. Assocs. Inc.*, No. 3:09-CV-130 (M.D. Ga. Nov. 3, 2016); *United States ex rel. McGuire v. Millennium Laboratories, Inc.*, No. 12-cv-10132 (D. Mass. Aug. 19, 2016) (and related cases); *United States ex rel. Doe v. Institute of Cardiovascular Excellence, PLLC*, Case No. 5:11-CV-406-OC-KRS (M.D. Fla. May 17, 2016) (and related cases); *United States ex rel. Bilotta v. Novartis Pharm.*

Corp., 50 F. Supp. 3d 497 (S.D.N.Y. 2014). The U.S. Department of Health and Human Services has issued “special fraud alerts” specifically warning about AKS violations in reimbursement requests for laboratory services for over twenty years. *See* Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014), reprinted at 79 Fed. Reg. 40,115 (July 11, 2014); Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), reprinted at 59 Fed. Reg. 65,372 (Dec. 19, 1994). There can be no question that the Government would likely refuse to pay a claim that it actually knows is the result of an AKS violation.

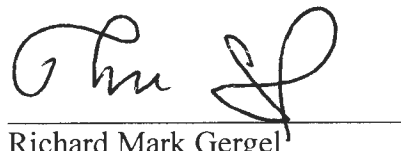
B. Medical Necessity

The parties do not appear to dispute that the representation that a laboratory service is medically necessary is material to the Government’s decision to pay a claim for the service. Indeed, the relevant Government agencies lack discretion to reimburse laboratory tests they know to be medically unnecessary. *E.g.*, 42 U.S.C. § 1395y (providing that “no payment may be made under [Medicare] part A or part B for any expenses incurred for items or services . . . (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”).

II. Conclusion

For the foregoing reasons, the Court **ACCEPTS** the Government’s proposed jury instruction 2.9 (Dkt. No. 755 at 12) and **DECLINES** Defendant’s proposed jury instruction number 19 (Dkt. No. 703 at 19).

AND IT IS SO ORDERED.



Richard Mark Gergel
United States District Court Judge

December 4, 2017
Charleston, South Carolina